

SPL Process ER/DL Meeting Meeting Minutes Nov 4, 2015

Chair of today's meeting: Herb O'Brien

Teleconference information:

USA Toll-Free: 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. SPL REMS Pilot Program

The FDA (Federal Register notice published on Oct 6th) is announcing a pilot project for the submission of final approved Risk Evaluation and Mitigation Strategies (REMS) and certain REMS summary information electronically in a standard Structured Product Labeling (SPL) format. Participation in the pilot is voluntary and is open to application holders of drugs with REMS.

- The pilot is intended to help application holders, FDA, and other interested stakeholders evaluate a potential approach to converting REMS into SPL format and evaluate the usefulness of the REMS information to be provided in SPL format. This project also will help provide FDA with feedback on these topics from pilot participants and other interested stakeholders.
- In order to participate, you need to have an active REMS.
- Volunteers interested in participating in the pilot should contact pilot staff by email at REMS_Standardization@fda.hhs.gov. The following information should be included in the request: Contact name, contact phone number, and contact email address. FDA will contact interested applicants to discuss the pilot. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot. FDA is also seeking comment from any stakeholder on its proposed approach for capturing REMS information in SPL format in this pilot, as described in section II.
- FDA will accept requests for participation in the REMS SPL pilot from October 6, 2015 to December 7, 2015. The pilot will proceed for 4 months. This pilot may be extended as resources and needs allow.

DATES: Submit requests to participate in the REMS SPL pilot from October 6, 2015 to

December 7, 2015. See the “Participation” section for instructions on how to submit a request to participate. The pilot will proceed for 4 months, from October 6, 2015 to February 3, 2016. This pilot may be extended as resources and needs allow.

REMS will be discussed by FDA (project lead Adam Kroetsch) at the SPL Tech Team meeting on Monday, November 9th. Gary Saner

- **He will present an overview of the REMS and more details on the pilot.**
- If you want to participate but are not on the tech team, you can still attend. Let Pat or Herb know and they'll forward your request to Gary Saner.

2. Issues with Images in X-Forms

The SPL site no longer uses Java inserting jpeg label images into the Package Label Principal Display Panel has become a tricky endeavor. They don't remain in the file after saving and reopening the file or they save in the file but display as a broken image link. This often necessitates several saving and reloading attempts before it saves correctly.

Further, they have removed the option to directly save the file locally as an .xml document. They are now downloaded as a .zip file which we must extract to the .xml file prior to submission through ESG. This extraction invariably removes the image and often makes the section “not well formed” in the words of the SPL support team. This also usually requires several saves and reloads for the section and image to load and thus save correctly. There is no guarantee that this will work either as I have had several product files in which the XForm saves and validates correctly but upon submission we receive errors back stating that the label image is not in the document.

Discussion:

- They have contacted SPL@fda.hhs.gov.

3. Helpful hints on Lot Distribution Reporting – Michael Fauntleroy (FDA)

- Submission process:
 - CBER:
 - Submit using the following category: SPL_LDD
 - Don't use: eBLA or Lot Distribution.
 - Otherwise the LDR files get misclassified. FDA then needs to locate these files and send them back up to the elist system.
 - The eCTD should still be submitted within the eCTD normal file structure.
 - CDER:
 - Submit using the following category: eCTD
- Caution: make sure that the file is named accordingly.

- For CDER files: When can you expect an acknowledgement?
 - Contact CDER: esub@fda.hhs.gov or Virginia Hussong
- **Michael will participate in our November 18 teleconference to answer our questions.**
 - **Send questions in advance to Herb, Mary Beth, and Pat. We will consolidate our questions and send them to Michael so that he can prepare responses.**

4. LDR Gateway and Submission of Files

The current guidance reads:

“IV. PROCESS

The lot distribution file should be included in eCTD Module 3, section 3.2.R Regional Information. Applicants should name the leaf title, “Lot-Distribution-Report-[Date of the submission].” The lifecycle for this file should be updated as appropriate, in accordance with the current eCTD₂ specification.

Lot distribution files should be formatted in the same electronic messaging standard used for drug registration and listing information and for the content of labeling for BLAs. This standard, known as Health Level Seven (HL7) Structured Product Labeling (SPL), allows information to be exchanged, searched, and combined with other data sources in a manner that supports health information technology initiatives to improve patient care.”

This guidance is not complete, if you follow it you will not receive a validation notice through the OC gateway. A special gateway needs to be set up where you will have a special ~~eLDD SPL~~ Option, if you use the correct submission method, the LDD SPL technical validation processing notice from the OC Gateway portal should be made available to you within minutes after the FDA SPL system has received the submission from CBER and has processed the LDD SPL file.

5. Lot Distribution Reports: Lot and Distribution SPL Kits

I have been notified that the FDA is still working on the the kit requirements for LDR and that directions will be issued in the form of an e-book. I have received several questions on issues with kits. If you are not tracking your kit at the package level, the only NDC product code that is need is the inner component product code for which the active ingredient is associated. **Mike Faunterloy** from the FDA LDR team will attend our next meeting.

6. Standard Approval Letter language regarding submission of SPL paper copies and posting of SPL:

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product

This is an OLD form letter which often creates confusion among sponsors. Lonnie has provided consult in the past to submit a “representative sample” of cartons. Most sponsors submit a carton (or label) for each strength, not container labels – and potentially if there are different types of packaging (bottle vs blisters). Same thing we do as CBER.

7. Unauthorized Registrations: Heads up and discussion about whether this has been an issue for companies (Dragan Obramavich).

From FDA's perspective, for registration purposes, listing the name and contact information for the U.S. agent in the registration is sufficient to "authorize" the agent. For its own business reasons, however, a facility may want to formalize its relationship with the agent with some sort of written agreement. Regardless of whether there is a formalized relationship between the facility and its U.S. agent, FDA does expect that the personnel from the facility will have verified that the person designated in the facility's registration as its U.S. agent is willing to serve as the agent.

However it does not prevent anyone from registering a site without your knowledge. For Drugs and Devices the registrations can be searched and companies can take action to remove unauthorized registrations or take any appropriate action. For Food Facilities companies have absolutely no idea they are registered if an unauthorized person registered the facility since these are considered confidential and not publicly available. Food Facility Registrations are also exempt from FOI.

In either case I think having unauthorized registrations pose a serious risk for our products because for each registration we can only be reactive.

Discussion:

- FDA is currently contacting companies that are registered but are not referenced in drug listings.